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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,168	11/21/2003	Gary A. Dahl	310307.00004	2342

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EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,168	DAHL ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/07*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the office action filed on May 11, 2007 has been considered and acknowledged.

Status

2. Claims 84-147 are pending. Claims 84, 93, 104, 111, 122-128 and 147 are amended. The amendment did not change the scope of the claims. The arguments and amendment are fully considered and found persuasive for the reasons that follow. The action is made Non-Final.

Informalities

3. The following informalities are noted:

(i) Claim 145 does not end with a full stop (.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 84-89, 91-92, 95-97, 100-110, 113-115, 118-127, 133-138, 140-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurn et al. (US 6,251,639) in view of Shibata et al. (Genome Research, Vol. 5, pp. 400-403, 1995).

Kurn et al. teach a method of 84, 104, 106, 122, for amplifying a target nucleic acid sequence, wherein the method comprises

(a) hybridizing a riboprimer (composite primer comprising RNA and DNA portion) to a DNA template comprising target nucleic acid sequence (see col. 4, line 28-33);

(b) extending the riboprimer with a DNA polymerase (see col. 4, line 37-38);

(c) cleaving the annealed riboprimer to the template and repeats primer extension, whereby multiple copies of the complementary sequence of the target nucleic acid are produced (see col. 4, line 38-44).

With regard to claim 85, 105, Kurn et al. teach that the method further comprises, prior to step (b), hybridizing a blocking oligonucleotide (termination polynucleotide sequence) to a region of the template that is 5' with respect to the hybridization of the riboprimer to the template (see col. 4, line 34-37).

With regard to claim 86, Kurn et al teach that the method is conducted under isothermal conditions (see col. 4, line 37-44, col. 11, line 64-67, col. 12, line 1-9).

With regard to claim 87-88, 146-147, Kurn et al. teach that he method further comprises attaching multiple copies produced in step c) onto a solid support to make a microarray and also

comprises a step of hybridizing multiple copies produced in step c) to oligonucleotide probe arrays (see col. 39, line 36-67, col. 40, line 1-13).

With regard to claim 89, Kurn et al. teach that the step b) comprises utilization of at least one type of labeled dNTP such that labeled extension products are generated (col. 5, line 50-67, col. 6, line 1-3).

With regard to claim 91, 109, 125-126, 145, Kurn et al. teach that the method utilizes one or more (plurality) of riboprimers (see col. 5, line 4-5, col. 8, line 29-47, col. 20, line 66-67).

With regard to claim 95-97, 113-115, 133, Kurn et al. teach that the entire composite primer is complementary to the 3-end of the target nucleic acid (col.20, line 54-65), or 5'-end portion of the riboprimer is not complementary to the target nucleic acid sequence, which can be copied by a second-primer extension (see col. 17, line 38-43, col. 10, line 22-45, col. 30, line 36-67).

With regard to claims 100-103, 118-121, 123-124, 135-138, Kurn et al. teach that the DNA polymerase is selected from the group consisting of Bst DNA polymerase and RNase H enzyme is thermostable RNase H (see col. 26, line 13-21, col. 50, line 11).

With regard to claim 104, 122, 141, Kurn et al. teach obtaining DNA comprising a target nucleic acid, obtaining a riboprimer, annealing the riboprimer to the target DNA, obtaining a strand-displacing DNA polymerase, extending riboprimer annealed to the DNA, obtaining the double-stranded complex, contacting the double-stranded complex with RNase H, annealing a second rib primer, extending the extension product and obtaining a second primer extension product (see col. 10, line 22-45, col. 36, line 58-61, col. 43, line 1-67, col. 44, line 1-67, col. 45, line 1-13).

With regard to claims 107-108, Kurn et al. teach detecting and quantization primer extension products (see col. 45, line 14-67, col. 46, line 1-5, col. 53, line 16-27).

With regard to claim 122, 142-144, Kurn et al. teach generating multiple copies of a polynucleotide sequence complementary to an RNA sequence with a RNA-dependent DNA polymerase (see col. 11, line 52-56, col. 33, line 49-63, col. 36, line 58-61, col. 31, line 10-36).

With regard to claim 134, Kurn et al. teach that the target RNA is mRNA (see col. 33, line 49-52).

With regard to claim 140, Kurn et al. teach that the enzyme that cleaves RNA in step b) cleaves RNA from RNA/DNA hybrid (see col. 34, line 25-26).

However, Kurn et al. did not specifically teach riboprimer comprising only ribonucleotides.

Shibata et al. teach RNA-primed PCR amplification, wherein Shibata et al. teach that the method comprises RNA primers comprising only oligoribonucleotides that prime the DNA synthesis (see page 400, col. 3, paragraph under RNA-primed PCR section, page 401, col. 1, line 1-13).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for amplifying a nucleic acid target sequence using riboprimers as disclosed by Kurn et al. in a manner as taught by Shibata et al. with the use of RNA primers for the purpose of priming DNA target at random sites. One skilled in the art would be motivated to combine the method of Kurn et al. with RNA primers as taught by Shibata et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in copying DNA inexpensively without previous knowledge of the

primer sequences because Shibata et al. explicitly taught that the use of RNA primers in priming DNA targets result in inexpensive method that requires no previous knowledge of primer sequences (see page 400, col. 1, paragraph 2) and such modification of the method would be obvious over the cited prior art.

B. Claims 90, 93-94, 98-99,111-112, 116-117, 128-132,139 rejected under 35 U.S.C. 103(a) as being unpatentable over Kurn et al. (US 6,251,639) in view of Dean et al (US 6,977,148).

Kurn et al. teach a method for amplifying a target nucleic acid as discussed above in section 3A. However, Kurn et al. did not specifically teach riboprimer comprising modified and random nucleotides.

Dean et al. teach a method for amplifying a target nucleic acid sequence, wherein the method comprises

(a) hybridizing a riboprimer (composite primer comprising RNA and DNA portion or RNA type primer) to a DNA / RNA template comprising target nucleic acid sequence (see col. 2, line 29-67, col. 3, line 1-9, col. 34, line 36-67);

(b) extending the riboprimer with a DNA polymerase (see col. 2, line 29-67, col. 34, line 36-51);

(c) cleaving the annealed riboprimer to the template and repeats primer extension, whereby multiple copies of the complementary sequence of the target nucleic acid are produced (see col. 34, line 36-67, col. 36, line 10-51).

With regard to claims 90, 92-93, Dean et al. teach that the riboprimer comprises random sequences, or primer comprising modified nucleotides which include 2' deoxy modifications and

peptide nucleic acid modifications (see col. 2, line 43-67, col. 3, line 1-9, col. 9, line 6-67, col. 10, line 1-67, col. 11, line 1-67, col. 12, line 1-67, col. 13, line 1-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for amplifying a nucleic acid target sequence using riboprimers as disclosed by Kurn et al. in a manner as taught by Dean et al. with the use of riboprimers comprising modified nucleotides for the purpose of increasing efficient priming of the target nucleic acid. One skilled in the art would be motivated to combine the method of Kurn et al. with modified riboprimers as taught by Dean et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in enhancing the stability of primer binding and exonuclease resistance which would increase efficient priming of the target nucleic acid because Dean et al. explicitly taught that the use of modified riboprimers in enhancing the stability of primer binding and exonuclease resistance which would increase efficient priming of the target nucleic acid (see col. 9, line 27-59) and such modification of the method would be obvious over the cited prior art.

Response to arguments:

5. With regard to the objection to the abstract of the disclosure, Applicants' amendment and arguments are fully considered and found persuasive and the objection is withdrawn herein inview of the amendment.

6. With regard to the rejection of claims 104-120 under 35 USC 112, second paragraph, Applicants' amendment and arguments are fully considered and found persuasive and the rejection is withdrawn herein in view of the amendment.

7. With regard to the rejection of claims 84-89, 91, 96-97, 100-109, 114-115, 118-126, 133-138, 140-147 under 35 USC 102(b) as being anticipated by Kurn et al. Applicants' arguments and amendment are fully considered and the rejection is withdrawn herein in view of the amendment.

8. With regard to the rejection of claims 84, 86-95, 98, 100-104, 106-113, 116, 118-132, 134-147 under 35 USC 102(b) as being anticipated by Dean et al., Applicants' arguments and the amendment are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment.

9. With regard to the rejection of claims 99, 117 under 35 USC 103(a) as being obvious over Kurn et al. in view of Berg et al. Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn herein in view of the amendment.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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Suryaprabha Chunduru
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER
7/20/07